AMENDMENTS TO THE CLAIMS

Applicants respectfully request that the application be amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

1. (cancelled)

2. (cancelled)

3. (cancelled)

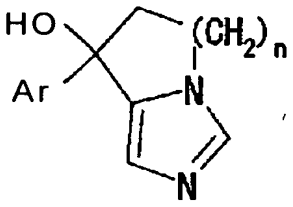
4. (cancelled)

5. (cancelled)

6. (cancelled)

7. (currently amended) A controlled release composition for oral administration, wherein

(A) a core containing (1) a physiologically active substance which is a compound represented by the formula:



(1)-A

wherein n is an integer of 1 to 3, and Ar is an aromatic ring which may be substituted, or a salt thereof, and (2) hydrophilic polymers selected from hydroxypropylcellulose~~, hydroxypropylmethylcellulose, methylcellulose, polyethylene oxide, sodium carboxymethylcellulose~~ and low-substituted hydroxypropylcellulose, which is coated with

(B) a coating layer containing (1) methacrylic acid copolymers as a enteric coating agent~~ selected from cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, hydroxymethylcellulose acetate succinate and methacrylic acid copolymers~~, (2) talc as a lubricant~~ selected from magnesium stearate, calcium stearate, talc, light anhydrous silicic acid, colloidal silica, synthetic aluminum silicate and magnesium~~

~~aluminometasilicate~~, and (3) a plasticizer selected from ~~acetyl tributyl citrate, acetyl triethyl citrate, castor oil, diacetylated monoglyceride, dibutyl sebacate, diethyl phthalate, glycerin, mono- and diacetylated monoglyceride,~~ polyethylene glycol~~, propylene glycol, triacetin~~ and triethyl citrate.

8. (currently amended) The controlled release composition according to claim ~~2~~ 7, wherein the release property of the physiologically' active substance in the absence of the coating layer is of rapid release.

9. (currently amended) The controlled release composition according to claim ~~2~~ 7, wherein the core is a controlled release matrix ~~which further comprises a hydrophilic polymer~~.

10. (cancelled)

11. (currently amended) The controlled release composition according to claim ~~2~~ 7, wherein the polymer in the coating layer exhibits pH-dependent or delayed-dissolution type water solubility.

12 (currently amended) The controlled release composition according to claim ~~2~~ 7, wherein the polymer in the coating layer is insoluble or sparingly soluble in water.

13. (cancelled)

14. (cancelled)

15. (cancelled)

16. (cancelled)

17. (cancelled)

18. (cancelled)

19. (cancelled)

20. (cancelled)

21. (cancelled)

22. (cancelled)

23. (currently amended) A controlled release composition for oral administration, wherein

(A) a core containing (1) (+)-6-(7-hydroxy-6,7-dihydro-5Hpyrrolo[1,2-c]imidazol-7-y1)-N-methy1-2-n- aphthamide or a salt thereof, and (2) a hydrophilic polymer selected from hydroxypropylcellulose, ~~hydroxypropylmethylcellulose, methylcellulose, polyethylene oxide, sodium carboxymethylcellulose~~ and low-substituted hydroxypropylcellulose, which is coated with

(B) a coating layer containing (1) methacrylic acid copolymers as an enteric coating agent ~~selected from cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, hydroxymethylcellulose acetate succinate and methacrylic acid copolymers~~, (2) talc as a lubricant ~~selected from magnesium stearate, calcium stearate, talc, light anhydrous silicic acid, colloidal silica, synthetic aluminum silicate and magnesium aluminometasilicate~~, and (3) a plasticizer selected from ~~acetyl tributyl citrate, acetyl triethyl citrate, castor oil, diacetylated monoglyceride, dibutyl sebacate, diethyl phthalate, glycerin, mono- and diacetylated monoglyceride,~~ polyethylene glycol ~~, propylene glycol, triacetin~~ and triethyl citrate.

24. (currently amended) The controlled release composition according to claim ~~2~~ 7, wherein the solubility (37°C) of the physiologically active substance with respect to 1st fluid for the disintegration test in the Japanese Phalmacopoeia is about 0.1 mg/mL or more.

25. (currently amended) The controlled release composition according to claim ~~9~~ 7, wherein the content of the hydrophilic polymer is about 3% to about 95% by weight.

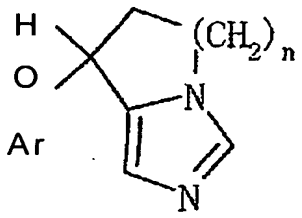
26. (currently amended) A controlled release composition, wherein the controlled release composition according to claim ~~2~~ 7 is coated with a coating layer which contains a physiologically active substance which is identical with or different from the physiologically active substance contained in the above-mentioned controlled release composition, and the release property of the physiologically active substance being of rapid release.

27. (currently amended) The controlled release composition according to claim ~~2~~ 7, which is used for prevention or treatment of prostate cancer or breast cancer.

28. (currently amended) A composition which comprises the controlled release composition according to claim ~~2~~ 7, combined with at least one other controlled release composition wherein a release rate of a physiologically active substance is different from that of the above-mentioned controlled release composition.

29. (previously presented) The composition according to claim 28, wherein the other controlled release composition contains a physiologically active substance whose solubility (37°C) with respect to 1st fluid for the disintegration test in the Japanese Pharmacopoeia is about 0.1 mg/mL or more.

30. (previously presented) The composition according to claim 29, wherein the physiologically active substance in the other controlled release composition is a compound represented by the folmula:



(I) -A

wherein n is an integer of 1 to 3, and Ar is an aromatic ring which may be substituted,

or a salt thereof.

31. (previously presented) The composition according to claim 30, which has the following dissolution characteristics:

1) in Method 2 of the dissolution test in the Japanese Phaimacopoeia (paddle method, rotation speed of paddle: 50 rpm, 37°C) using 900 mL of 1st fluid for the disintegration test in the Japanese Phailoacopoeia, the dissolution rate of the physiologically active substance from the controlled release composition at 15 minutes after initiation of the test is less than 10%, and

2) in Method 2 of the dissolution test in the Japanese Pharmacopoeia (paddle method, rotation speed of paddle: 50 rpm, 37°C) using 900 mL of 2nd fluid for the disintegration test in the Japanese Pharmacopoeia, the dissolution rate of the physiologically active substance from the controlled release composition at 24 hours after initiation of the test is 20% or more.

32. (previously presented) The composition according to claim 28, wherein the release property of the physiologically active substance in the other controlled release composition is of rapid release.

33. (previously presented) The composition according to claim 28, wherein the other controlled release composition is prepared by coating a core containing a physiologically active substance with a coating layer containing a polymer which exhibits pH-dependent or delayed-dissolution type water solubility.

34. (previously presented) The composition according to claim 28, which is used for prevention or treatment of prostate cancer or breast cancer.

35. (new) The controlled release composition according to claim 7, which has the following dissolution characteristics:

1) in Method 2 of the dissolution test in the Japanese3 Pharmacopoeia (paddle method, rotation speed of paddle: 50 rpm, 37°C) using 900 mL of 1st fluid for the disintegration test in the Japanese Pharmacopoeia, the dissolution rate of the physiologically active substance from the controlled release composition at 15 minutes after initiation of the test is less than 10%, and

2) in Method 2 of the dissolution test in the Japanese Pharmacopoeia (paddle method, rotation speed of paddle: 50 rpm, 37°C0 using 900 mL of 2nd fluid for the disintegration test in the Japanese Pharmacopoeia, the dissolution rate of the physiologically active substance from the controlled release composition at 24 hours after initiation of the test is 40% or more.